UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
7405 CHEMICAL CONTROL DIVISION

212d301

[redacted]

[redacted]

Re: Prenotice Communication 2580

Dear [redacted]:

This responds to your 21 December 1994 letter to my staffer, David Schutz, regarding whether certain antisera can be considered to be naturally-occuring substances under the Toxic Substances Control Act (TSCA) Chemical Substance Inventory (Inventory) regulations at 40 Code of Federal Regulations (CFR) §710.4(b). Naturally occurring substances which are "...(i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means..." were considered to be automatically included on the TSCA Inventory as described. To qualify, such substances may be removed from nature only by natural means. This precludes the use of solvents, other than water, for the extraction of naturally-occurring substances.

The situation you describe is that, after rabbits have been injected with immunogens, whole blood is withdrawn and cells are separated and discarded. The antiserum is precipitated from the serum by solution of a high concentration of salt. The EPA has determined that the use of a high concentration of salt constitutes processing other than by (by) manual, mechanical, or gravitational means, thus extraction of antisera through this method does not meet the definition of a naturally-occurring substance. Therefore, a premanufacture notice (PMN) would be required for the antisera if they are not already listed on the TSCA Inventory.

CONCURRENCE				
SYMBOL	7405	7405	7406	7405
SURNAME	Schutz, D DS	Hetfield, C CYH	Bickart, P BLG	Cushmac, M MC
DATE	January 18, 1995	1/19/95	1.20.95	1-20-95

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In your letter to Mr. Schutz, you also asked for guidance on appropriate application of the Research and Development (R&D) and Test Marketing exemptions for distribution of material to potential clients considering development of test kits.

R&D includes synthesis of new substances as well as analysis, experimentation or research on new or existing chemical substances. A substance must be the focus of R&D itself or be used in an R&D activity focussing on another chemical substance. Reagents and chemical substances to be used as standards for chemical analysis in laboratories are considered as substances that fall into the latter category.

The Agency agrees that the development of test kits for use of a substance to analyze for environmental pollutants would qualify as an R&D activity; therefore, based on the information you have provided, the R&D exemption is applicable. However, all procedural and recordkeeping provisions of the R&D exemption at 40 CFR §720.36 and §720.78 must be maintained for the R&D exemption to be considered valid. As well, the general distribution of chemical substances to consumers does not constitute R&D. The R&D exemption does not exclude from the exemption the sale of an R&D substance: manufacturers and processors may derive compensation from the sale of substance such as reagents and chemical standards. Much of the above discussion may be found in the *New Chemical Information Bulletin* Exemptions for Research and Development and Test Marketing (1986-1, November 1986, Office of Toxic Substances), which should be of value to you, and which is available from the TSCA Hotline at 202-554-1404.

You asked if material produced for R&D undertaken in Government-funded projects can now be sold. It would depend on whether there was a commercial link at the time the substance was manufactured as an R&D substance. You should review what is considered to be noncommercial R&D at 40 CFR §720.30(i). However, nothing in your letter suggests that the substance(s) was/were developed solely for Government use without any eventual commercial purpose. If a substance is not otherwise considered to have been manufactured for noncommercial R&D only, only the uses described at 40 CFR §720.36(d) and (e) may be made of it without filing PMN.

You further raised the question of the test marketing exemption (TME), and when it could be considered applicable. Several points must be considered in distinguishing R&D activity from test marketing activity. Again, you should consult the *New Chemical Information Bulletin* 1986 article Exemptions for Research and Development and Test Marketing, referenced above, but it does not appear that the TME would be useful unless you are examining the market acceptability of an antiserum as an environmental testing agent.

In your facsimile to Mr. Schutz, you described the potential test kits/assays to be developed as "articles". Please consult 40 CFR §720.3(c) for a definition of "article": it seems likely that, though components of the test kit may be articles under this definition, a test kit consisting of several items could not be a (singular) article.

Should you have any additional questions pertaining to this issue, please contact my staff member Dave Schutz, at (202) 260-8994.

Sincerely,

Mary Cushmac

Mary Cushmac, Chief
Policy and Administrative